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APPLICATION NUMBER:

216820Orig1s000

CLINICAL REVIEW(S)

CLINICAL REVIEW MEMO

Application Type	505(b)(2) NDA
Application Number(s)	216820
Priority or Standard	Standard
Submit Date(s)	March 30, 2022
Received Date(s)	March 30, 2022
PDUFA Goal Date	January 30, 2023
Division/Office	Division of Imaging and Radiation Medicine/Office of Specialty Medicine
Review Completion Date	December 20, 2023
Established/Proper Name	Kit for the Preparation of Technetium Tc 99m Mertiatide
(Proposed) Trade Name	Kit for the Preparation of Technetium Tc 99m Mertiatide
Pharmacologic Class	Radioactive diagnostic agent
Applicant	Jubilant DraxImage Inc., dba Jubilant Radiopharma
Dosage form	Powder for injection
Applicant proposed Dosing Regimen	(b) (4)
Applicant Proposed Indication(s)/Population(s)	
Applicant Proposed SNOMED CT Indication Disease Term	446536001 | Technetium (99m-Tc) mertiatide (substance)
Recommended Indication(s)/Population(s)	Kit for the Preparation of Technetium Tc 99m Mertiatide Injection, after radiolabeling with technetium-99m, is indicated for use in the diagnosis of congenital and acquired renal abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients aged 30 days and older. The product is a diagnostic aid in providing renal function, split function, renal angiograms, and renogram curves for whole kidney and renal cortex.
Recommended SNOMED CT Indication Disease Term	44513007 | Congenital anomaly of the kidney (disorder) 236423003 | Renal impairment (disorder) 204967008 | Renal pelvis and ureter obstructive defects (disorder)

	95570007 | Kidney stone (disorder)
Recommended Dosing Regimen	Adult The recommended dose in adult patients is 185 MBq to 370 MBq (5 mCi to 10 mCi) as an intravenous bolus injection. Pediatric The recommended dose in pediatric patients aged 30 days and older is 2.6 MBq/kg to 5.2 MBq/kg (0.07 mCi/kg to 0.14 mCi/kg) of actual body weight with a minimum dose of 37 MBq (1 mCi) as an intravenous bolus injection.

Regulatory History

(b) (4)

On October 15, 2021, a type C meeting request was submitted to NDA 216820 to inquire whether a 505(b)(2) NDA, with reliance on Technescan MAG3 as a listed drug (LD), might be an appropriate regulatory pathway for this drug. After discussion with Office of Generic Drugs, the division agreed that it may be submitted as a 505(b)(2) application and noted that the application would require information to establish a scientific bridge to the LD. NDA 216820 was submitted on March 30, 2022.

Review

The differences between the Applicant's product from the LD are the hydration status of the stannous chloride (dihydrate for the Applicant's drug, anhydrous for the LD) and that the proposed product does not use sodium hydroxide for pH adjustment. Because the amount of (b) (4) . Concerning the use of sodium hydroxide, the final product has the same pH as the LD and the Applicant has provided details of the manufacturing process whereby there is no need to use sodium hydroxide for pH adjustment.

The scientific bridge to the LD was reviewed by Biopharmaceutics, and the reviewer concluded:

Based on the totality of the information provided, the proposed drug product, NDA 216820 (Kit for the Preparation of Technetium Tc 99m Meriatide Lyophilized Powder for Solution) for intravenous administration is adequately bridged to the listed drug (LD), NDA 019882 (TechneScan MAG3™) in accordance with 21 CFR §320.24(b)(6) and an in vivo pharmacokinetic study is not needed.

As an adequate bridge has been established, reliance on FDA's findings of safety and effectiveness for Technescan MAG3 is considered sufficient support from a clinical perspective. No clinical data were submitted in this application, and none are needed.

Labeling

The listed drug prescribing information is in non-PLR format, and the Applicant was required to adapt their prescribing information into PLR format. Clinical advised clarifying changes to the draft labeling for the dosing and administration instructions, including dosimetry, and to the lactation and pediatric use subsections of section 8. Refer to the ADL labeling review for details.

Recommendation

Approval is recommended.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SHANE C MASTERS
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